

**REMARKS**

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow. Applicant thanks the Examiner for allowing the subject matter of claims 6-9.

Prior to the Reply, claims 1-27 were pending. By way of the present Reply, claims 1, 3, 5-15, and 17-19 are amended and claims 2 and 4 are cancelled. Claims 1, 3, and 5-27 are now pending. Of these claims, claims 16 and 20-27 are withdrawn from consideration. Favorable reconsideration of the application is respectfully requested.

**Drawing Acceptance**

Applicant notes that box 10(a) is not checked on form PTOL-326 (Rev. 08-06). Applicant, therefore, respectfully requests that in the next Office communication to Applicant's agent, the Office state that the drawings are accepted.

**Rejections under 35 U.S.C. § 112**

Claims 1-15 and 17-19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.<sup>1</sup> The claims have been amended where appropriate. Reconsideration and withdrawal of the 35 U.S.C. § 112 rejection is respectfully requested.

**Claim Interpretation**

Claim 1 is addressed regarding 35 U.S.C. § 112, 6<sup>th</sup> paragraph. Claim 1 has been amended as appropriate. Reconsideration and withdrawal of the Office's assertions on page 4 of the Office Action, section 5 are respectfully requested.

**Rejection of claims 1, 5, 10-12, 15, 17, and 19 based on Voellmicke**

Claims 1, 5, 10-12, 15, 17, and 19 are rejected under 35 U.S.C. § 102(a) as being anticipated by U.S. Patent No. 7,175,336.

A claim is only anticipated if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. (*Verdegaal Bros. v.*

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<sup>1</sup> Applicant notes that page 2 of the Office Action states that claims 1-15 and 1-19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicant respectfully asserts that the reference to claims 1-15 and 1-19 is a clerical error, as the substance of pages 2-3 of the Office Action pertaining to the 35 U.S.C. § 112, second paragraph, rejection only address claims 1, 2, 6-8, 13, 15, 17, and 18, and claim 16 is withdrawn.

*Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See generally M.P.E.P. § 2131). Voellmicke fails to satisfy the requirements of 35 U.S.C. § 102.

Specifically, Voellmicke fails to disclose, “a mixing arrangement configured to mix a first component with a second, liquid component; and a dispensing arrangement configured to dispense the mixed material, wherein the individual components are disposed in respective containers that are arranged side by side, wherein a closure or a connecting channel is selectively provided in a transfer area between the outlet area of the container configured to store the second, liquid component and the liquid inlet of the container configured to store the first component, wherein the mixing arrangement is arranged in the container for the first component that is separated from the dispensing arrangement, wherein the mixing arrangement includes a mixing rod with a mixing member that is movable back and forth and rotatable in the container, and wherein the mixing rod includes a predetermined breaking point,” as recited in claim 1.

According to an exemplary embodiment, a device and method for storing, mixing, and dispensing components is provided, that allows a simple handling and arrangement of containers while the components are fully separated during storage, and a simple control of the introduction of the second, liquid component into the first component, and that offers a wide range of applications such as external aspiration or introduction of a liquid into the dispensing device.

Voellmicke is directed to a manifold for mixing biomedical fluids. (Voellmicke, abstract). Voellmicke discloses a manifold 1 comprising first and second input ports 9, 10 where each port is adapted for attachment to delivery syringes. (Voellmicke, col. 5, lines 14-31, Figs. 1a and 5). Thus, Voellmicke discloses a separate manifold to which syringes can be attached individually so that each syringes out-inlet has a port in the manifold. Therefore, Voellmicke discloses a complex handling and arrangement of a manifold and syringes.

On page 6 of the Office Action, the Office correctly identifies that Voellmicke fails to disclose a mixing rod with a mixing member being perforated or cut out mixing disk. (Office Action, pg. 6). Voellmicke fails to disclose a mixing rod with a mixing member being perforated or cut out mixing disk. Additionally, Voellmicke fails to disclose a mixing arrangement at all. Rather, Voellmicke only discloses mixing by shaking a syringe or by flow of a material by a piston. (Voellmicke, col. 9, lines 55-66, col. 14, lines 39-50, col. 16, lines

30-45). Thus, Voellmicke fails to disclose, “a mixing arrangement configured to mix a first component with a second, liquid component; and a dispensing arrangement configured to dispense the mixed material, wherein the individual components are disposed in respective containers that are arranged side by side, wherein a closure or a connecting channel is selectively provided in a transfer area between the outlet area of the container configured to store the second, liquid component and the liquid inlet of the container configured to store the first component, wherein the mixing arrangement is arranged in the container for the first component that is separated from the dispensing arrangement, wherein the mixing arrangement includes a mixing rod with a mixing member that is movable back and forth and rotatable in the container, and wherein the mixing rod includes a predetermined breaking point,” as recited in claim 1.

Assuming arguendo that Voellmicke discloses a mixing arrangement, Voellmicke fails to disclose, “wherein the mixing arrangement is arranged in the container for the first component that is separated from the dispensing arrangement,” as recited in claim 1. Voellmicke discloses delivery syringes 62 and 72. (Voellmicke, col. 9, lines 42-45). The delivery syringes are filled with PRP and thrombin and are inserted into delivery ports 9 and 11. (Voellmicke, col. 9, lines 42-45). Fluid retention chamber 82, which before mixing has an empty bore 61, is inserted into input port 3. (Voellmicke, col. 9, lines 50-51). When the plungers 65, 75 of delivery syringes 62, 72 are depressed, the fluids in the delivery syringes 62, 72 are delivered through openings 63, 73 which are inserted into delivery ports 9, 11 and the fluids advance into the opening 83 of the fluid retention chamber 82 so that the fluids may gel. (Voellmicke, col. 9, lines 55-51). In short, Voellmicke discloses that the fluid in delivery syringes 62 and 72 is not mixed in either delivery syringe 62, 72, but rather is mixed upon leaving the delivery syringes 62, 72 and entering the previously empty fluid retention chamber 82. Thus, Voellmicke fails to disclose, “wherein the mixing arrangement is arranged in the container for the first component that is separated from the dispensing arrangement,” as recited in claim 1.

Claims 5, 10-12, 15, 17, and 19 depend from independent claim 1 and are therefore allowable at least for the same reasons that claim 1 is allowable. Reconsideration and withdrawal of the 35 U.S.C. § 102 rejection is respectfully requested.

Rejection of claims 2-4 based on Voellmicke and McGill

Claims 2-4 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Voellmicke in view of U.S. Patent No. 7,524,103 (“McGill”). Claims 2 and 4 have been cancelled and the subject matter of claims 2 and 4 included in claim 1. Claim 1 is allowable at least for the aforementioned reasons. Additionally, McGill fails to remedy the deficiencies of Voellmicke.

McGill discloses a device 700 for mixing and dispensing a bone cement that includes a tubular body 702, a rod 726, a mixing disk 712, and a movable ejection piston 718. (McGill, col. 10, line 66 – col. 11, line 5). McGill discloses that to operate the mixing/dispensing device 700, all ingredients of bone cement must be in the internal mixing chamber 708, where the user mixes the ingredients together by moving the rod 726 back and forth relative to the tubular body 702. (McGill, col. 11, lines 47-54). The rod 726, piston 718, and mixing disk 712 move distally together to dispense the cement. (McGill, col. 11, line 64 – col. 12, line 6). In short, McGill discloses that the mixing and dispensing device are the same thing. McGill also discloses that the mixing and dispensing device are located in the same container. Thus, McGill fails to disclose, “a mixing arrangement configured to mix a first component with a second, liquid component; and a dispensing arrangement configured to dispense the mixed material, wherein the individual components are disposed in respective containers that are arranged side by side, wherein a closure or a connecting channel is selectively provided in a transfer area between the outlet area of the container configured to store the second, liquid component and the liquid inlet of the container configured to store the first component, wherein the mixing arrangement is arranged in the container for the first component that is separated from the dispensing arrangement,” as recited in claim 1.

Additionally, McGill discloses that the rod 726 may be threaded and designed to mate with a bracket. (McGill, col. 12, lines 7-9). The bracket has a quick release mechanism so that after mixing, the rod is moved distally through the tubular body 702. (McGill, col. 11, lines 9-15). Thus, McGill discloses that the rod 726 may be designed to mate with a bracket so that the rod 726 moves distally through the tubular body 702 when the quick release mechanism is engaged. McGill, therefore, discloses that the rod 726 moves distally through the tubular body 702 when the mated bracket’s quick release mechanism is engaged. McGill fails to disclose that the quick release mechanism is a breaking point, but rather that it is the

point at which the rod moves distally. McGill, therefore, fails to disclose, "wherein the mixing rod includes a predetermined breaking point," as recited in claim 1.

Claim 3 depends from independent claim 1 and is therefore allowable at least for the same reasons that claim 1 is allowable. Reconsideration and withdrawal of the 35 U.S.C. § 103 rejection is respectfully requested.

Conclusion

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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